IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE: DIET DRUGS (PHENTERMINE/ FENFLURAMINE/DEXFENFLURAMINE) PRODUCTS LIABILITY LITIGATION	)	MDL NO. 1203
THIS DOCUMENT RELATES TO:	)	
SHEILA BROWN, et al.	)	
v.	)	CIVIL ACTION NO. 99-20593
AMERICAN HOME PRODUCTS CORPORATION	)	2:16 MD 1203

MEMORANDUM IN SUPPORT OF SEPARATE PRETRIAL ORDER NO. 8380

Bartle, C.J. January 7, 2010

Roberta Ebbert ("Ms. Ebbert" or "claimant"), a class member under the Diet Drug Nationwide Class Action Settlement Agreement ("Settlement Agreement") with Wyeth,[1] seeks benefits from the AHP Settlement Trust ("Trust").[2] Based on the record developed in the show cause process, we must determine whether claimant has demonstrated a reasonable medical basis to support her claim for Matrix Compensation Benefits ("Matrix Benefits").[3]

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1. Prior to March 11, 2002, Wyeth was known as American Home Products Corporation.

2. Alexander Ebbert, Ms. Ebbert's son, also has submitted a derivative claim for benefits.

3. Matrix Benefits are paid according to two benefit matrices (Matrix "A" and Matrix "B"), which generally classify claimants for compensation purposes based upon the severity of their medical conditions, their ages when they are diagnosed, and the

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To seek Matrix Benefits, a claimant must first submit a completed Green Form to the Trust. The Green Form consists of three parts. The claimant or the claimant's representative completes Part I of the Green Form. Part II is to be completed by the claimant's attesting physician, who must answer a series of questions concerning the claimant's medical condition that correlate to the Matrix criteria set forth in the Settlement Agreement. Finally, claimant's attorney must complete Part III of the Green From if claimant is represented.

In April 2002, claimant submitted a completed Green Form to the Trust signed by her attesting physician J. Jeffrey Rich, M.D. Based on an echocardiogram dated November 29, 2001, Dr. Rich attested in Part II of Ms. Ebbert's Green Form that she suffered from moderate mitral regurgitation, moderate aortic regurgitation,[4] and a reduced ejection fraction in the range of

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3.(...continued)
presence of other medical conditions that also may have caused or contributed to a claimant's valvular heart disease ("VHD"). See Settlement Agreement §§ IV.B.2.b. & IV.B.2.d.(1)-(2). Matrix A-1 describes the compensation available to Diet Drug Recipients with serious VHD who took the drugs for 61 days or longer and who did not have any of the alternative causes of VHD that made the B matrices applicable. In contrast, Matrix B-1 outlines the compensation available to Diet Drug Recipients with serious VHD who were registered as having only mild mitral regurgitation by the close of the Screening Period or who took the drugs for 60 days or less or who had factors that would make it difficult for them to prove that their VHD was caused solely by the use of these diet drugs.

4. As Ms. Ebbert's claim does not present any of the complicating factors necessary to receive Matrix Benefits for damage to her aortic valve, her level of aortic regurgitation is
(continued...)

50% to 60%.[5] Based on such findings, claimant would be entitled to Matrix A-1, Level II benefits[6] in the amount of $492,142.[7]

In the report of claimant's echocardiogram, Kian S. Kooros, M.D., the reviewing cardiologist, described claimant's level of mitral regurgitation as moderate. Under the definition set forth in the Settlement Agreement, moderate or greater mitral regurgitation is present where the Regurgitant Jet Area ("RJA") in any apical view is equal to or greater than 20% of the Left Atrial Area ("LAA"). See Settlement Agreement § I.22. Dr. Kooros also stated that claimant had "[n]ormal global contractility of the left ventricle with a normal ejection fraction of 58%." An ejection fraction is considered reduced for

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4.(...continued)
not relevant to this claim. See Settlement Agreement § IV.B.2.c.(2)(a).

5. Dr. Rich also attested that claimant suffered from New York Heart Association Functional Class I symptoms. This condition, however, is not at issue in this claim.

6. Although Dr. Rich also stated that claimant suffered from mitral annular calcification ("MAC"), which requires the payment of reduced Matrix Benefits under the Settlement Agreement, the Trust subsequently determined that there was no reasonable medical basis for Dr. Rich's finding. Thus, if the claim were to be found payable, the Trust determined that Matrix A, and not Matrix B, would apply.

7. Under the Settlement Agreement, a claimant is entitled to Level II benefits for damage to the mitral valve if he or she is diagnosed with moderate or severe mitral regurgitation and one of five complicating factors delineated in the Settlement Agreement. See Settlement Agreement § IV.B.2.c.(2)(b). A reduced ejection fraction is one of the complicating factors needed to qualify for a Level II mitral valve claim. Id. § IV.B.2.c.(2)(b)iv).

purposes of a mitral valve claim if it is measured as less than or equal to 60%. See id. § IV.B.2.c.(2)(b)iv).

In November 2003, the Trust forwarded the claim at issue to Mikhail Torosoff, M.D., one of its auditing cardiologists. In audit, Dr. Torosoff concluded that there was no reasonable medical basis for Dr. Rich's finding that claimant had moderate mitral regurgitation. In particular, Dr. Torosoff found that the "[m]id-systolic mitral regurgitant jet recorded on videotape qualifies for mild MR with MR jet height >1 cm from valve, and by visual assessment RJA/LAA between 5 and 20%." Dr. Torosoff also concluded that there was no reasonable medical basis for Dr. Rich's finding that claimant had a reduced ejection fraction. Dr. Torosoff stated that "[a] comprehensive review of all available long and short axis views suggests normal LV ejection fraction, estimated to be between 65% and 70%."

Based on the auditing cardiologist's diagnosis, the Trust issued a post-audit determination denying Ms. Ebbert's claim. Pursuant to the Rules for the Audit of Matrix Compensation Claims ("Audit Rules"), claimant contested this adverse determination.[8]

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8. Claims placed into audit on or before December 1, 2002 are governed by the Policies and Procedures for Audit and Disposition of Matrix Compensation Claims in Audit, as approved in Pretrial Order ("PTO") No. 2457 (May 31, 2002). Claims placed into audit after December 1, 2002 are governed by the Audit Rules, as approved in PTO No. 2807 (Mar. 26, 2003). There is no dispute that the Audit Rules contained in PTO No. 2807 apply to Ms. Ebbert's claim.

In contest, claimant argued that Dr. Torosoff "guestimated" her level of her ejection fraction without any "math [or] documented measurements." Claimant also argued that the auditing cardiologist "employ[ed] again a vague 'guess'" to determine her level of mitral regurgitation. Finally, claimant asserts that "[t]he auditing cardiologist refutes the opinions of two other Cardiologists, both of whom were paid and recommended by the Trust ...."[9]

Based on claimant's contest, the Trust submitted her claim to Dr. Torosoff for a second review. Dr. Torosoff confirmed his previous conclusion that there was no reasonable medical basis for Dr. Rich's findings of moderate mitral regurgitation and a reduced ejection fraction. According to Dr. Torosoff, he "re-measured multiple 4-chamber view frames" and, based on these measurements, he concluded that "the true ratio of RJA/LAA is $3.132/17.496cm^2$ or 17.9%." With respect to claimant's ejection fraction, Dr. Torosoff stated that:

> I calculated the ejection fraction under the following formula: $(EDD^2-ESD^2)/EDD^2*100+K$, where K=10% for a normal apex, A.E. Weyman *Principles and Practice of Echocardiography*, page 606, 1994. My calculation of the ejection fraction was as follows: $(5.2^2-3.4^2)/5.2^2*100+10=67\%$. This value is within range of 65-70%, which I estimated at audit.

The Trust then issued a final post-audit determination, again denying Ms. Ebbert's claim. Claimant disputed this adverse

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9. Claimant's attesting physician participated in the Screening Program established under the Settlement Agreement. See infra.

determination and requested that the claim proceed to the show cause process established in the Settlement Agreement. See Settlement Agreement § VI.E.7; PTO No. 2807, Audit Rule 18(c). The Trust then applied to the court for issuance of an order to show cause why Ms. Ebbert's claim should be paid. On November 17, 2004, we issued an order to show cause and referred the matter to the Special Master for further proceedings. See PTO No. 4142 (Nov. 17, 2004).

Once the matter was referred to the Special Master, the Trust submitted its statement of the case and supporting documentation. Claimant then served a response upon the Special Master. The Trust submitted a reply on June 1, 2005. Under the Audit Rules, it is within the Special Master's discretion to appoint a Technical Advisor[10] to review claims after the Trust and claimant have had the opportunity to develop the Show Cause Record. See Audit Rule 30. The Special Master assigned a Technical Advisor, Gary J. Vigilante, M.D., F.A.C.C., to review the documents submitted by the Trust and claimant, and prepare a report for the court. The Show Cause Record and Technical

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10. A "[Technical] [A]dvisor's role is to act as a sounding board for the judge-helping the jurist to educate himself in the jargon and theory disclosed by the testimony and to think through the technical problems." Reilly v. U.S., 863 F.2d 149, 158 (1st Cir. 1988). In cases, such as here, where there are conflicting expert opinions, a court may seek the assistance of the Technical Advisor to reconcile such opinions. The use of a Technical Advisor to "reconcil[e] the testimony of at least two outstanding experts who take opposition positions" is proper. Id.

Advisor's Report are now before the court for final determination. Id. Rule 35.

The issue presented for resolution of this claim is whether claimant has met her burden in proving that there is a reasonable medical basis for the attesting physician's findings that she had moderate mitral regurgitation and a reduced ejection fraction. See id. Rule 24. Ultimately, if we determine that there was no reasonable medical basis for the answers in claimant's Green Form that are at issue, we must confirm the Trust's final determination and may grant such other relief as deemed appropriate. See id. Rule 38(a). If, on the other hand, we determine that there was a reasonable medical basis for the answers, we must enter an Order directing the Trust to pay the claim in accordance with the Settlement Agreement. See id. Rule 38(b).

In support of her claim, Ms. Ebbert argues that "careful scrutiny of the entire file would reveal the obvious," that there is a reasonable medical basis for her attesting physician's findings of moderate mitral regurgitation and a reduced ejection fraction. Claimant also submitted her Gray

Form[11] and correspondence from the Trust[12] and she resubmitted her contest materials.

In response, the Trust argues that claimant fails to satisfy her burden of proof by arguing in "conclusory fashion." The Trust further asserts that, by failing to dispute the auditing cardiologist's detailed conclusions, claimant cannot establish a reasonable medical basis for her attesting physician's findings of moderate mitral regurgitation and a reduced ejection fraction.

The Technical Advisor, Dr. Vigilante, reviewed claimant's echocardiogram and concluded that, while there was a reasonable medical basis for the attesting physician's finding of moderate mitral regurgitation, there was no reasonable medical

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11. The Gray Form is for Class Members to: (1) claim Fund A Settlement Benefits based upon an echocardiogram performed after September 30, 1999; (2) document a diagnosis of FDA Positive or mild mitral regurgitation to preserve the right to seek future matrix level benefits; or (3) document the results of an echocardiogram for purposes of an intermediate or back-end opt-out.

12. In one of these letters, the Trust informed claimant that Dr. Torosoff had been disqualified by the Court. On the first page of this letter, there is a hand-written note stating "[t]he Trust had to know that these physicians had vested interest." Pursuant to PTO No. 4245, for any claim that was audited by a disqualified auditing cardiologist, the claimant was provided with an opportunity to have his or her claim re-audited by an independent auditing cardiologist. Each claimant was given thirty days after the date of notice from the Trust to make this selection. See PTO No. 4245 (Dec. 15, 2004). Claimant declined to select re-audit by stating that she had "no desire to seek further evaluation of [her] echocardiogram." As claimant declined to accept a re-audit, she is bound by her election only to challenge the conclusions of the auditing cardiologist.

basis for the attesting physician's finding of a reduced ejection fraction. Specifically, Dr. Vigilante determined that:

> The left ventricle was completely normal in size and in contractility. Indeed, there was vigorous contractility of all segments of the left ventricle. There were no regional wall motion abnormalities. In addition, motion of the left ventricular apex was normal. The left ventricular ejection fraction was calculated at 65% via Simpson's Method.

In response to the Technical Advisor's Report, Ms. Ebbert argues that Dr. Vigilante "ignore[s] his own findings." In addition, claimant submits that Dr. Vigilante should have explained why he used a method (Simpson's Method) for calculating claimant's level of ejection fraction that differed from the method used by Dr. Rich and Dr. Kooros. She further contends that because two cardiologists reviewed her echocardiogram and found that she had a reduced ejection fraction, there is a reasonable medical basis for her claim.

After reviewing the entire show cause record, we find that claimant's arguments regarding her level of ejection fraction are without merit. We disagree with claimant that Dr. Vigilante ignored his findings. To the contrary, Dr. Vigilante specifically found that claimant's "left ventricle was completely normal in size and in contractility" and that there was "vigorous contractility of all segments of the left ventricle."

We also reject claimant's assertion that Dr. Vigilante should have explained why he used Simpson's Method rather than

the method used by Dr. Rich and Dr. Kooros. As an initial matter, we previously have relied on reports where the Technical Advisor used Simpson's Method to evaluate a claimant's ejection fraction. See, e.g., PTO No. 7219 (May 24, 2007) and PTO No. 7282 (June 29, 2007). In addition, although claimant relies on the findings of her own cardiologists, the attesting physician's representation cannot have a reasonable medical basis where the Technical Advisor concluded that claimant's ejection fraction was greater than the required threshold.[13]

Finally, we reject claimant's assertion that she is entitled to Matrix Benefits because the echocardiogram that forms the basis of the claim was conducted in the Screening Program for Fund A Benefits under the Settlement Agreement.[14] See Settlement Agreement § IV.A. Claimant's reliance on the echocardiogram obtained as a result of the Screening Program is misplaced.

The Settlement Agreement clearly provides that the sole benefit that a class member is entitled to receive for a favorable echocardiogram under the Screening Program is a limited amount of medical services or a limited cash payment:

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13. Claimant previously challenged the auditing cardiologist's conclusion regarding her ejection fraction by asserting that the auditing cardiologist's findings should be disregarded because he failed to provide measurements of her ejection fraction. In her show cause submission, claimant abandoned this argument, apparently because in his second review, Dr. Torosoff, although not required to, made specific measurements of claimant's ejection fraction, which further established that claimant is not entitled to Matrix Benefits.

14. Claimant raised this argument during the contest phase of the audit process.

> All Diet Drug Recipients in Subclass 2(b) and those Diet Drug Recipients in Subclass 1(b) who have been diagnosed by a Qualified Physician as FDA Positive by an Echocardiogram performed between the commencement of Diet Drug use and the end of the Screening Period, will be entitled to receive, at the Class Member's election, either (I) valve-related medical services up to $10,000 in value to be provided by the Trust; or (ii) $6,000 in cash.

Settlement Agreement, § IV.A.1.c. Thus, by the plain terms of the Settlement Agreement, a Screening Program echocardiogram does not automatically entitle a claimant to Matrix Benefits.

Indeed, this conclusion is confirmed by the Settlement Agreement provisions concerning claimants eligible for Matrix Benefits. Specifically, claimants with a diagnosis of FDA Positive or mild mitral regurgitation merely become eligible to seek Matrix Benefits. See Settlement Agreement § IV.B.1. Further, adopting claimant's position would be inconsistent with the Settlement Agreement's provisions governing the audit of claims for Matrix Benefits (Settlement Agreement § VI.E.) as well as this Court's decision in PTO No. 2662 (Nov. 26, 2002), which mandated a 100 percent audit requirement for all claims for Matrix Benefits. Id. at 13 ("We find that good cause exists under the Settlement Agreement to modify the Trust's procedures to order it to designate all Fund B claims for audit."). As nothing in the Settlement Agreement supports the conclusion that a favorable Screening Program echocardiogram for purposes of Fund A benefits results in an immediate entitlement to Matrix

Benefits, we decline claimant's request to interpret the Settlement Agreement in this fashion.

For the foregoing reasons, we conclude that claimant has not met her burden in proving that there is a reasonable medical basis for finding that she has a reduced ejection fraction. Therefore, we will affirm the Trust's denial of Ms. Ebbert's claim for Matrix Benefits and the related derivative claim submitted by her son.[15]

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15. We need not address whether there is a reasonable medical basis for the attesting physician's finding of moderate mitral regurgitation. Without establishing the existence of a reduced ejection fraction, claimant cannot meet the criteria delineated in the Settlement Agreement for Level II benefits. See Settlement Agreement § IV.B.2.c.(2)(b).